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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
Office Action Summary	10/660,122	ECKER ET AL.	
	Examiner	**Art Unit**	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 23-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 23-43 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/29/03; 11/24/03;

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Claim Interpretation

1. As a preliminary issue, the claims must be interpreted before proceeding with the prior art analysis. The phrase "molecular mass" appears repeatedly in the claims and specification but no definition of this term was found. At page 9, the term is used in a manner which indicates that "any technique known in the art" can be used for the mass measurement. Therefore, the term is broadly read to encompass any mode of determination of molecular mass, including mass determinations by sizing on gel electrophoresis, as well as mass spectrometry, which is the clearly preferred mode of analysis.

The term "database" is also repeatedly used. The term is not defined in the specification. The ordinary meaning of "database" is a "collection of information". Any collection of information, such as a set of reference nucleic acid positions, would satisfy this claim limitation.

Finally, the claim uses the term "intervening variable region" and requires that this region exhibit no more than 5% sequence identity among members of the viral family. Since no length for the variable region is required, a single SNP between two members, would represent a region of 0% homology and would meet the limitations of the claims. So this limitation is interpreted as requiring the presence of at least one nucleotide polymorphism between the viruses being analyzed.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 23, 25, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Figueiredo et al (Am. J. Trop. Med. Hyg. (1998) 59(3):357-362).

Figueiredo teaches a method of claims 23 and 30 of providing viral bioagent characterizing information (see abstract), comprising:

(a) *amplifying nucleic acid from said virus with a pair of primers to conserved regions of a housekeeping gene that is conserved among members of a viral family to produce an amplification product* (see page 358, column 1, where primers were selected in the highly conserved NS5 and 3'NS regions of Flavivirus and where RT-PCR was performed on culture fluid),

wherein the amplification product corresponds to a bioagent identifying amplicon (see page 360, figure 3, where the amplification products are detected)

and wherein the conserved regions have at least 80% sequence identity among the virus family which flank an interveining variable region which exibits no greater than 5% sequence identity among members of the viral family (see attached BLAST search where the first Flavivirus primer on page 358 under the primer subheading has 100% sequence identity with 190 different Genbank accession numbers).

(b) *measuring the molecular mass of said amplification product* (see page 360, figure 3, where the molecular weight of several bands is determined).

(c) *comparing the molecular mass of the amplification product with known molecular masses of known bioagent identifying amplicons of members of said viral family wherein a match of molecular mass of the amplification product with a known mass of a known bioagent identifying amplicon of a member of the viral family indicates the identity of the virus* (see figures 1-3, where molecular masses are shown and compared with one another).

With regard to claims 25, 32, Flaviviruses are threat agents since they include yellow fever (see page 357, columns 1 and 2)(also see page 36 of specification, which lists yellow fever as a biowarfare agent).

4. Claims 23, 25, 26, 30, 32, 33, 37, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujioka et al (J. Virol. Meth. (1995) 51:253-258).

Fujioka teaches a method of claims 23 and 30 of providing viral bioagent characterizing information (see abstract), comprising:

(a) *amplifying nucleic acid from said virus with a pair of primers to conserved regions of a housekeeping gene that is conserved among members of a viral family to produce an amplification product* (see page 254, where primers were selected in the highly conserved noncoding regions of eneterovirus genomes and where RT-PCR was performed on virus solutions),

wherein the amplification product corresponds to a bioagent identifying amplicon (see page 256, figure 1, where the amplification products are detected)

and wherein the conserved regions have at least 80% sequence identity among the virus family which flank an interveining variable region which exibits no greater than 5% sequence identity among members of the viral family (The first primer on page 254 is 100% conserved among 100 coxsackievirus, poliovirus, echovirus isolates as shown by the BLAST search).

(b) *measuring the molecular mass of said amplification product* (see page 256, figure 2, where the molecular weight of several bands is determined).

(c*) comparing the molecular mass of the amplification product with known molecular masses of known bioagent identifying amplicons of members of said viral family wherein a match of molecular mass of the amplification product with a known mass of a known bioagent identifying amplicon of a member of the viral family indicates the identity of the virus* (see page 256, figure 2, where the molecular patterns on SSCP are shown and see abstract where SSCP analysis is recognized as useful for rapid diagnosis of enteroviral infection).

With regard to claim 37, Fijioka teaches analysis of a sequence of 154 basepairs, which is "about" 150 bases in length (see abstract).

With regard to claims 25, 32, 39, polioviruses are threat agents (see abstract) (also see page 36 of the specification which lists poliovirus as a biological warfare threat agent).

With regard to claims 26, 33, 40, Fujioka teaches detection of different subtypes (see figures 1 and 2 where Cocksackie viruses subtype CVA7 was distinguished from CVA9 in lanes 2 and 3 of figure 2, for example).

5. Claims 23, 25-27, 30, 32-34, 37 and 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Jurinke et al (Genetic Analysis: Biomolecular Engineering (1996) 13:67-71).

Jurinke teaches a method of claims 23 and 30 of providing viral bioagent characterizing information (see abstract), comprising:

(a) *amplifying nucleic acid from said virus with a pair of primers to conserved regions of a housekeeping gene that is conserved among members of a viral family to produce an amplification product* (see page 68, where primers were selected in the highly conserved regions of the HBV genomes and where RT-PCR was performed on virus solutions),

wherein the amplification product corresponds to a bioagent identifying amplicon (see page 256, figure 1, where the amplification products are detected)

and wherein the conserved regions have at least 80% sequence identity among the virus family which flank an interveining variable region which exibits no greater than 5% sequence identity among members of the viral family (The two primers are more than 80% conserved as shown by the BLAST search).

(b) *measuring the molecular mass of said amplification product* (see page 68, subheading "MALDI-TOF MS", where Jurinke measures the molecular mass with mass spectrometry).

(c) *comparing the molecular mass of the amplification product with known molecular masses of known bioagent identifying amplicons of members of said viral family wherein a match of molecular mass of the amplification product with a known mass of a known bioagent identifying amplicon of a member of the viral family indicates the identity of the virus* (see page 70, where the mass of sample 1 is compared to sample 3 to demonstrate the presence of HBV in the sample).

With regard to claim 37, Jurinke teaches analysis of a sequence of 67 basepairs, which is between 45 and 150 bases in length (see page 69, column 2).

With regard to claims 25, 32, 39, HBV are threat agents (see abstract) (also see page 36 of the specification which lists Hepatitis viruses as biological warfare threat agents).

With regard to claims 26, 33, 40, Jurinke teaches detection of different subtypes (see page 71, column 1, "determining different HBV subtypes by different masses of the HBV related PCR products").

With regard to claims 27, 34, 41, Jurinke teaches measurement by mass spectrometry (see page 68, subheading "MALDI-TOF MS").

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 24, 31 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujioka et al (J. Virol. Meth. (1995) 51:253-258) in view of Campbell et al (J. Virol. Methods (1996) 57:175-179).

Fujioka teaches a method of claims 23 and 30 of providing viral bioagent characterizing information (see abstract), comprising:

(a) *amplifying nucleic acid from said virus with a pair of primers to conserved regions of a housekeeping gene that is conserved among members of a viral family to produce an amplification product* (see page 254, where primers were selected in the

highly conserved noncoding regions of eneterovirus genomes and where RT-PCR was performed on virus solutions),

wherein the amplification product corresponds to a bioagent identifying amplicon (see page 256, figure 1, where the amplification products are detected)

and wherein the conserved regions have at least 80% sequence identity among the virus family which flank an interveining variable region which exibits no greater than 5% sequence identity among members of the viral family (The first primer on page 254 is 100% conserved among 100 coxsackievirus, poliovirus, echovirus isolates as shown by the BLAST search).

(b) *measuring the molecular mass of said amplification product* (see page 256, figure 2, where the molecular weight of several bands is determined).

(c*) comparing the molecular mass of the amplification product with known molecular masses of known bioagent identifying amplicons of members of said viral family wherein a match of molecular mass of the amplification product with a known mass of a known bioagent identifying amplicon of a member of the viral family indicates the identity of the virus* (see page 256, figure 2, where the molecular patterns on SSCP are shown and see abstract where SSCP analysis is recognized as useful for rapid diagnosis of enteroviral infection).

With regard to claim 37, Fijioka teaches analysis of a sequence of 154 basepairs, which is “about” 150 bases in length (see abstract).

Fujioka does not teach the use of multiple sets of primers to improve the detection assay.

Campbell teaches the use of multiple primers in order to detect every variant (see page 178, column 1).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Fujioka to use multiple primer pairs as taught by Campbell since Fujioka recognizes the problem that mismatches in the primer binding region may prevent PCR amplification (see page 257, "There is concern about the frequency of the mutation at the 5' non-coding region where the PCR target locates, although it is considered one of the most conserved regions in the enterovirus genome") and Campbell provides a solution by using an additional set of primers to identify variants which the first set might miss, where Campbell notes "By using both sets of primers it is highly unlikely that any variant will go undetected (see page 178, column 1).". Thus, an ordinary practitioner, concerned with the problem of missing variants with a mutation in the conserved region of a virus, can resolve this concern by repeating the assay with additional primer sets as taught by Campbell, who teaches that the use of additional primer sets will result in improved detection of all variants.

9. Claims 24, 31 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jurinke et al (Genetic Analysis: Biomolecular Engineering (1996) 13:67-71) in view of Campbell et al (J. Virol. Methods (1996) 57:175-179).

Jurinke teaches a method of claims 23 and 30 of providing viral bioagent characterizing information (see abstract), comprising:

(a) *amplifying nucleic acid from said virus with a pair of primers to conserved regions of a housekeeping gene that is conserved among members of a viral family to produce an amplification product* (see page 68, where primers were selected in the highly conserved regions of the HBV genomes and where RT-PCR was performed on virus solutions),

wherein the amplification product corresponds to a bioagent identifying amplicon (see page 256, figure 1, where the amplification products are detected)

and wherein the conserved regions have at least 80% sequence identity among the virus family which flank an interveining variable region which exibits no greater than 5% sequence identity among members of the viral family (The two primers are more than 80% conserved as shown by the BLAST search).

(b) *measuring the molecular mass of said amplification product* (see page 68, subheading "MALDI-TOF MS", where Jurinke measures the molecular mass with mass spectrometry).

(c) *comparing the molecular mass of the amplification product with known molecular masses of known bioagent identifying amplicons of members of said viral family wherein a match of molecular mass of the amplification product with a known*

mass of a known bioagent identifying amplicon of a member of the viral family indicates the identity of the virus (see page 70, where the mass of sample 1 is compared to sample 3 to demonstrate the presence of HBV in the sample).

With regard to claim 37, Jurinke teaches analysis of a sequence of 67 basepairs, which is between 45 and 150 bases in length (see page 69, column 2).

Jurinke does not teach the use of multiple sets of primers to improve the detection assay.

Campbell teaches the use of multiple primers in order to detect every variant (see page 178, column 1).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Jurinke to use multiple primer pairs as taught by Campbell since Campbell notes "By using both sets of primers it is highly unlikely that any variant will go undetected (see page 178, column 1).". Thus, an ordinary practitioner, concerned with the problem of missing variants with a mutation in the conserved region of a virus, can resolve this concern by repeating the assay with additional primer sets as taught by Campbell, who teaches that the use of additional primer sets will result in improved detection of all variants.

10. Claims 28, 29, 35, 36, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujioka et al (J. Virol. Meth. (1995) 51:253-258) in view of Kilpatrick et al (J. Clin. Microbiol. (1996) 34(12):2990-2996).

Fujioka teaches a method of claims 23 and 30 of providing viral bioagent characterizing information (see abstract), comprising:

(a) *amplifying nucleic acid from said virus with a pair of primers to conserved regions of a housekeeping gene that is conserved among members of a viral family to produce an amplification product* (see page 254, where primers were selected in the highly conserved noncoding regions of eneterovirus genomes and where RT-PCR was performed on virus solutions),

wherein the amplification product corresponds to a bioagent identifying amplicon (see page 256, figure 1, where the amplification products are detected)

and wherein the conserved regions have at least 80% sequence identity among the virus family which flank an interveining variable region which exibits no greater than 5% sequence identity among members of the viral family (The first primer on page 254 is 100% conserved among 100 coxsackievirus, poliovirus, echovirus isolates as shown by the BLAST search).

(b) *measuring the molecular mass of said amplification product* (see page 256, figure 2, where the molecular weight of several bands is determined).

(c) *comparing the molecular mass of the amplification product with known molecular masses of known bioagent identifying amplicons of members of said viral family wherein a match of molecular mass of the amplification product with a known*

mass of a known bioagent identifying amplicon of a member of the viral family indicates the identity of the virus (see page 256, figure 2, where the molecular patterns on SSCP are shown and see abstract where SSCP analysis is recognized as useful for rapid diagnosis of enteroviral infection).

With regard to claim 37, Fijioka teaches analysis of a sequence of 154 basepairs, which is "about" 150 bases in length (see abstract).

Fujioka does not teach the use of inosine in the primers to improve the detection assay.

Kilpatrick teaches the use of inosine containing primers for detection of a more polioviruses (see page 2994, column 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Fujioka to use inosine as taught by Kilpatrick since Fujioka recognizes the problem that mismatches in the primer binding region may prevent PCR amplification (see page 257, "There is concern about the frequency of the mutation at the 5' non-coding region where the PCR target locates, although it is considered one of the most conserved regions in the enterovirus genome") and Kilpatrick provides a solution by using inosine to improve specificity, where Kilpatrick notes "In our hands, PCR assays using the degenerate panPV PCR primers were positive for a very diverse sample of poliovirus genotypes, had excellent

diagnostic specificities and had template sensitivities comparable to those obtained with nondegenerate primers (see page 2994, column 2)". Thus, an ordinary practitioner, concerned with the problem of missing variants with a mutation in the conserved region of a virus, can resolve this concern by using inosine containing primers as taught by Kilpatrick, who teaches that the use of inosine containing primer sets will result in improved detection of a diverse sample of genotypes.

11. Claims 28, 29, 35, 36, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jurinke et al (Genetic Analysis: Biomolecular Engineering (1996) 13:67-71) in view of Kilpatrick et al (J. Clin. Microbiol. (1996) 34(12):2990-2996).

Jurinke teaches a method of claims 23 and 30 of providing viral bioagent characterizing information (see abstract), comprising:

(a) *amplifying nucleic acid from said virus with a pair of primers to conserved regions of a housekeeping gene that is conserved among members of a viral family to produce an amplification product* (see page 68, where primers were selected in the highly conserved regions of the HBV genomes and where RT-PCR was performed on virus solutions),

wherein the amplification product corresponds to a bioagent identifying amplicon (see page 256, figure 1, where the amplification products are detected)

and wherein the conserved regions have at least 80% sequence identity among the virus family which flank an interveining variable region which exibits no greater than

5% sequence identity among members of the viral family (The two primers are more than 80% conserved as shown by the BLAST search).

(b) *measuring the molecular mass of said amplification product* (see page 68, subheading "MALDI-TOF MS", where Jurinke measures the molecular mass with mass spectrometry).

(c) *comparing the molecular mass of the amplification product with known molecular masses of known bioagent identifying amplicons of members of said viral family wherein a match of molecular mass of the amplification product with a known mass of a known bioagent identifying amplicon of a member of the viral family indicates the identity of the virus* (see page 70, where the mass of sample 1 is compared to sample 3 to demonstrate the presence of HBV in the sample).

With regard to claim 37, Jurinke teaches analysis of a sequence of 67 basepairs, which is between 45 and 150 bases in length (see page 69, column 2).

Jurinke does not teach the use of inosine in the primers to improve the detection assay.

Kilpatrick teaches the use of inosine containing primers for detection of a more polioviruses (see page 2994, column 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Jurinke to use inosine as taught

by Kilpatrick since Kilpatrick teaches that using inosine improves detection, where Kilpatrick notes "In our hands, PCR assays using the degenerate panPV PCR primers were positive for a very diverse sample of poliovirus genotypes, had excellent diagnostic specificities and had template sensitivities comparable to those obtained with nondegenerate primers (see page 2994, column 2)". Thus, an ordinary practitioner would have been motivated to use inosine containing primers as taught by Kilpatrick, who teaches that the use of inosine containing primer sets will result in improved detection of a diverse sample of genotypes.

Double Patenting

12. Claims 23-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 59,60,62,63,66,69-76 and 79-94 of copending Application No. 10/156,608 in view of Jurinke et al (Genetic Analysis: Biomolecular Engineering (1996) 13:67-71).

Claims 59,60,62,63,66,69-76 and 79-94 of copending Application No. 10/156,608 teach detection of bacterial bioagents by contacting nucleic acid from the bioagent with at least one pair of primers which hybridize to flanking sequences of the nucleic acid, wherein the flanking sequences flank a variable nucleic acid sequence of the bioagent; amplifying the variable nucleic acid sequence to produce an amplification product; determining the molecular mass of the amplification product by mass spectrometry; and comparing the molecular mass of the amplification product to calculated or measured molecular masses of analogous amplitkation products of one or more known bacterial bioagents present in a database comprising 19 or more molecular masses, with the

proviso that sequencing of the amplification product is not used to identify the bacterial bioagent.

Claim 92 teaches the use of inosine.

Claims 59,60,62,63,66,69-76 and 79-94 of copending Application No. 10/156,608 do not teach detection of viruses.

Jurinke teaches a method of claims 23 and 30 of providing viral bioagent characterizing information (see abstract), comprising:

(a) *amplifying nucleic acid from said virus with a pair of primers to conserved regions of a housekeeping gene that is conserved among members of a viral family to produce an amplification product* (see page 68, where primers were selected in the highly conserved regions of the HBV genomes and where RT-PCR was performed on virus solutions),

wherein the amplification product corresponds to a bioagent identifying amplicon (see page 256, figure 1, where the amplification products are detected)

and wherein the conserved regions have at least 80% sequence identity among the virus family which flank an interveining variable region which exibits no greater than 5% sequence identity among members of the viral family (The two primers are more than 80% conserved as shown by the BLAST search).

(b) *measuring the molecular mass of said amplification product* (see page 68, subheading “MALDI-TOF MS”, where Jurinke measures the molecular mass with mass spectrometry).

(c) *comparing the molecular mass of the amplification product with known molecular masses of known bioagent identifying amplicons of members of said viral family wherein a match of molecular mass of the amplification product with a known mass of a known bioagent identifying amplicon of a member of the viral family indicates the identity of the virus* (see page 70, where the mass of sample 1 is compared to sample 3 to demonstrate the presence of HBV in the sample).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to detect viruses using the method of Claims 59,60,62,63,66,69-76 and 79-94 of copending Application No. 10/156,608 since Jurinke teaches that viruses such as HBV are an important target for diagnostic and therapeutic applications (see page 67).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 23-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 10/660,997. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims discuss viral biowarfare agents. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of claims 1-28 of copending Application No. 10/660,997 in order to detect organisms of interest such as Yellow Fever virus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Given the large number of related cases which show up on PALM, many of which are abandoned, Applicant is requested to comply with 37 CFR 1.56 by identification of copending applications, particularly applications close to issuance, which raise double patenting issues.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637

3/7/06